Unique Device Identification (UDI)

FDA Small Business
Regulatory Education for Industry (REdI)
Silver Spring, Maryland
September 30, 2015

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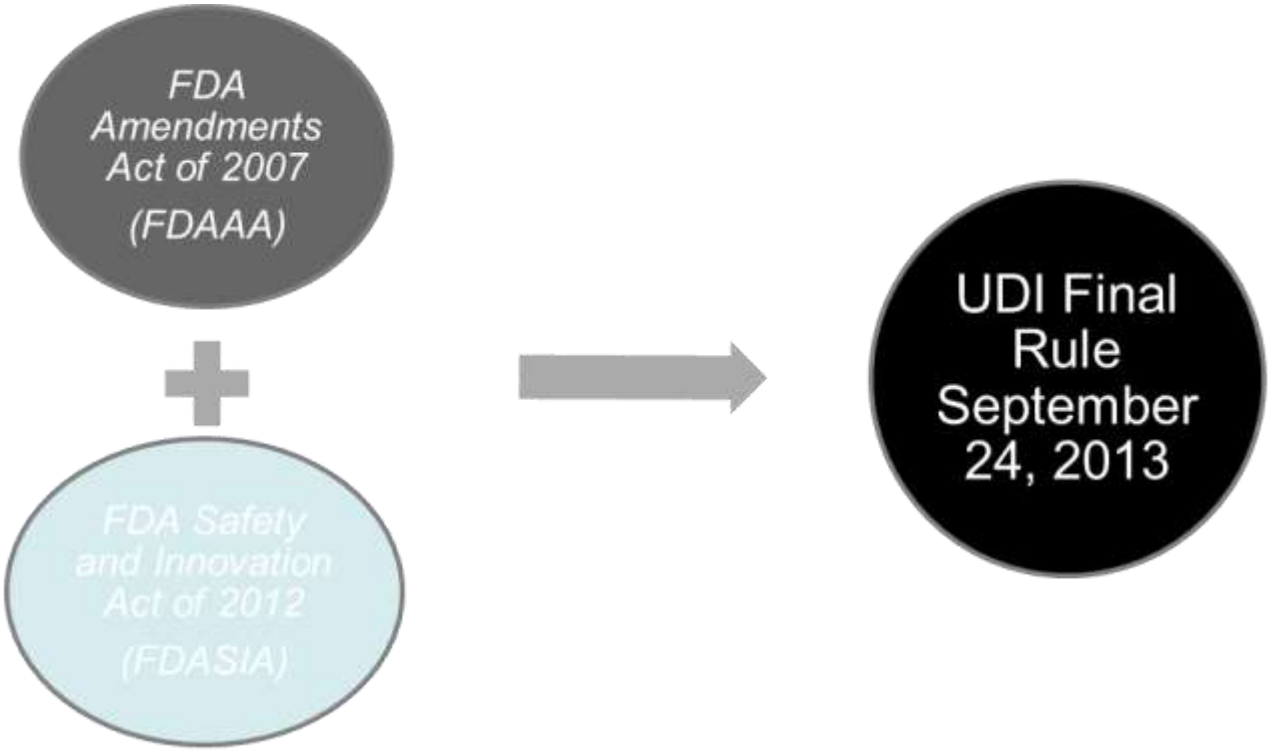
Presentation Overview

- UDI Program background including a summary of the program objectives and basic requirements
- UDI labeling labeling requirements: what is a UDI, what is a labeler, the issuing agencies
- Data submission requirements and public access to this data through AccessGUDID
- UDI compliance dates and general and individual exceptions and alternatives to UDI labeling requirements
- Additional resources
- Questions and Answers

Statutes and Regulation



Unique Identification of Products is Not New

Example of a serialized National Drug Code (sNDC)

NDC		SERIAL NUMBER
55555 666 77	+	11111111111111111111
labeler code + product code + package code		unique, up to 20 characters

The Unique Device Identification Program

Applies to devices placed in commercial distribution after the applicable compliance date

Devices
201(h) of FD&C Act

…instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory…

Commercial Distribution
21 CFR 807.3(b)

…distribution of a device intended for human use which is held or offered for sale…

Objectives of the Unique Device Identification Program

"Establish a system to adequately identify devices through distribution and use"

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls

"Adequately Identify"

Summary of Basic UDI Requirements

Device label and device packages must bear a UDI

Key data for these devices must be submitted to GUDID

Four Steps to a Successful UDI Program

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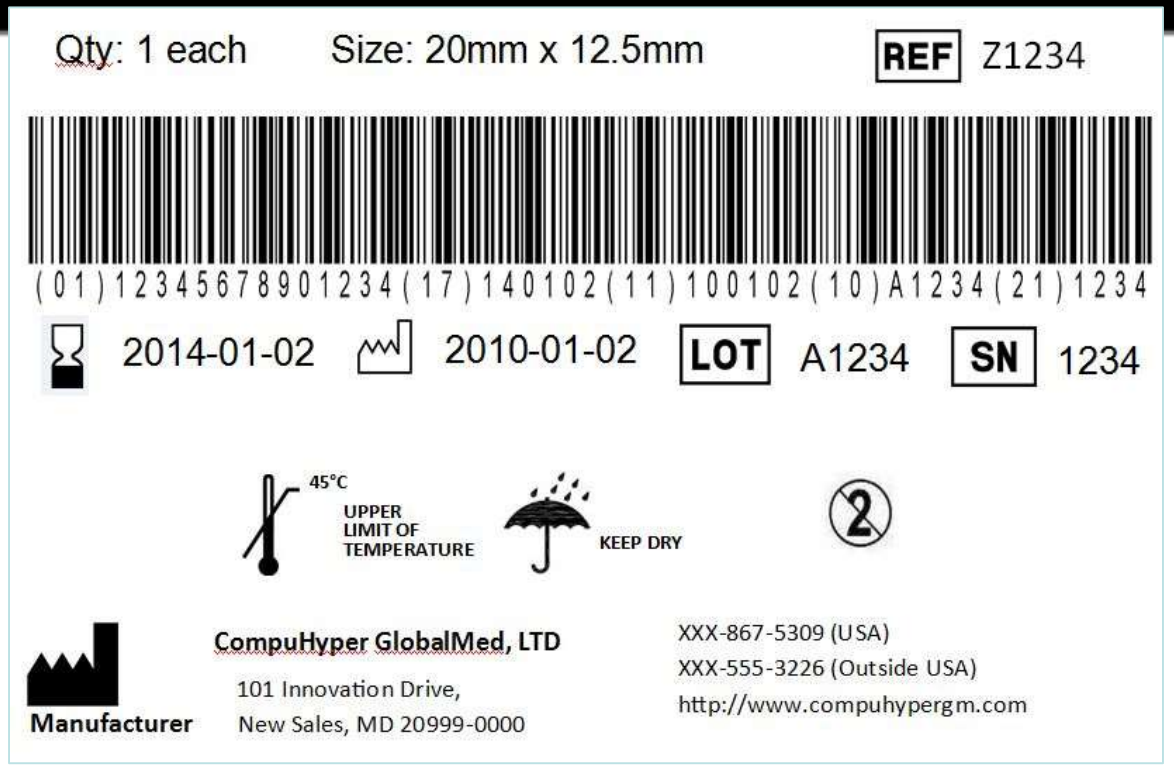
Label

"Label" means a "display of written, printed, or graphic matter upon the immediate container of any article…" 21 USC 321(k)



What is a Unique Device Identifier (UDI)?

Is a unique numeric or alphanumeric code;

Displayed in both human readable (plain text) and machine readable (AIDC) form;

that consists of two parts:

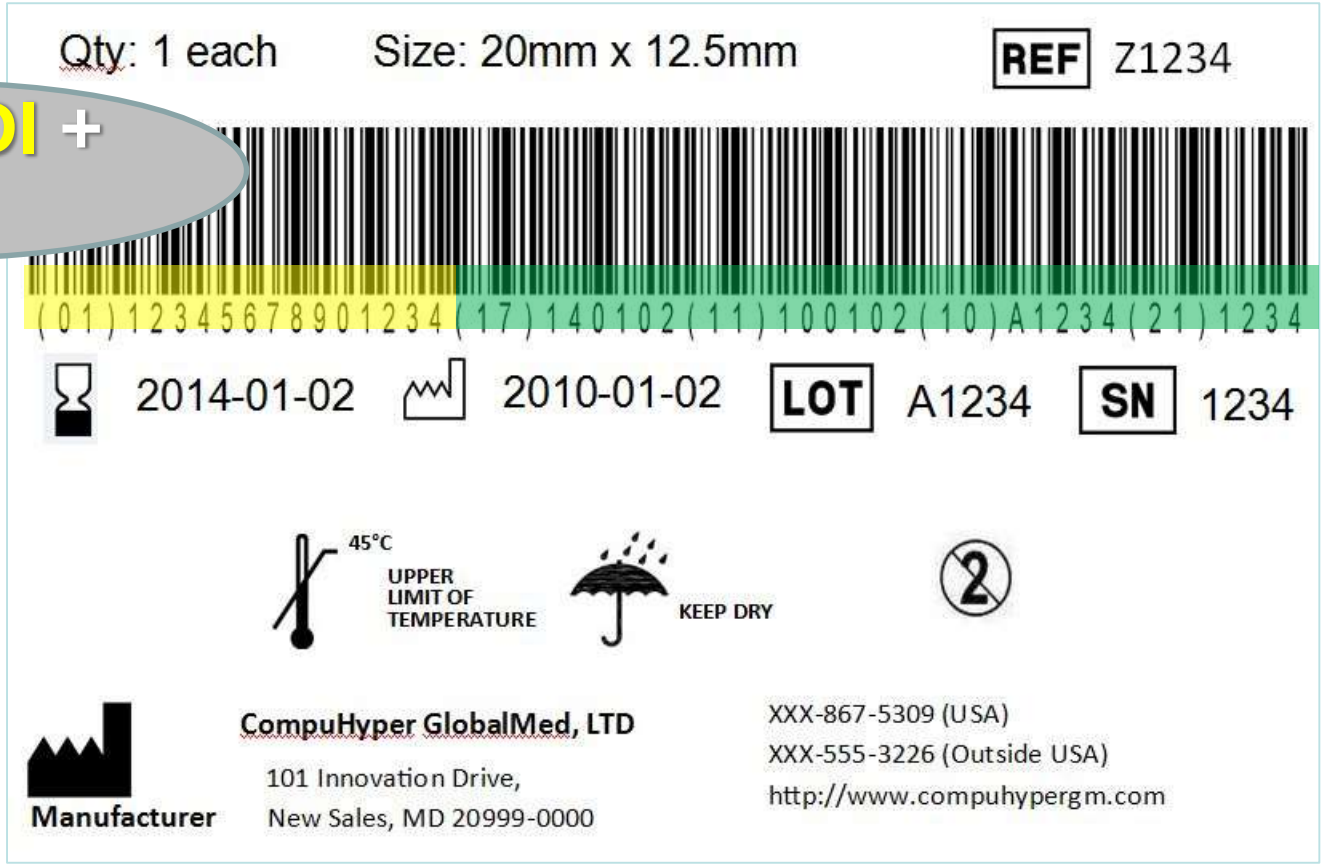
Device Identifier (**DI**)	Production Identifier(s) (**PI**)

UDI Example

Required on the device label, packaging or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

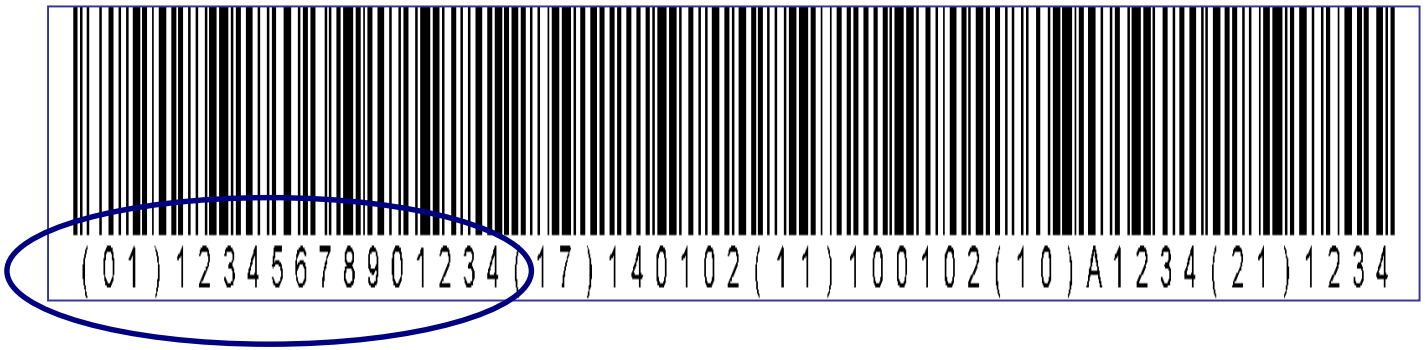
UDI = DI + PI



Device Identifier (DI)

- Mandatory, fixed portion of a UDI that identifies the specific **version or model** of a device and the **labeler** of that device

- Entered in GUDID



Production Identifier (PI)

Production Identifier(s) (PI) is a conditional, variable portion of a UDI

- Not required for class I devices

Includes (when on the device label):

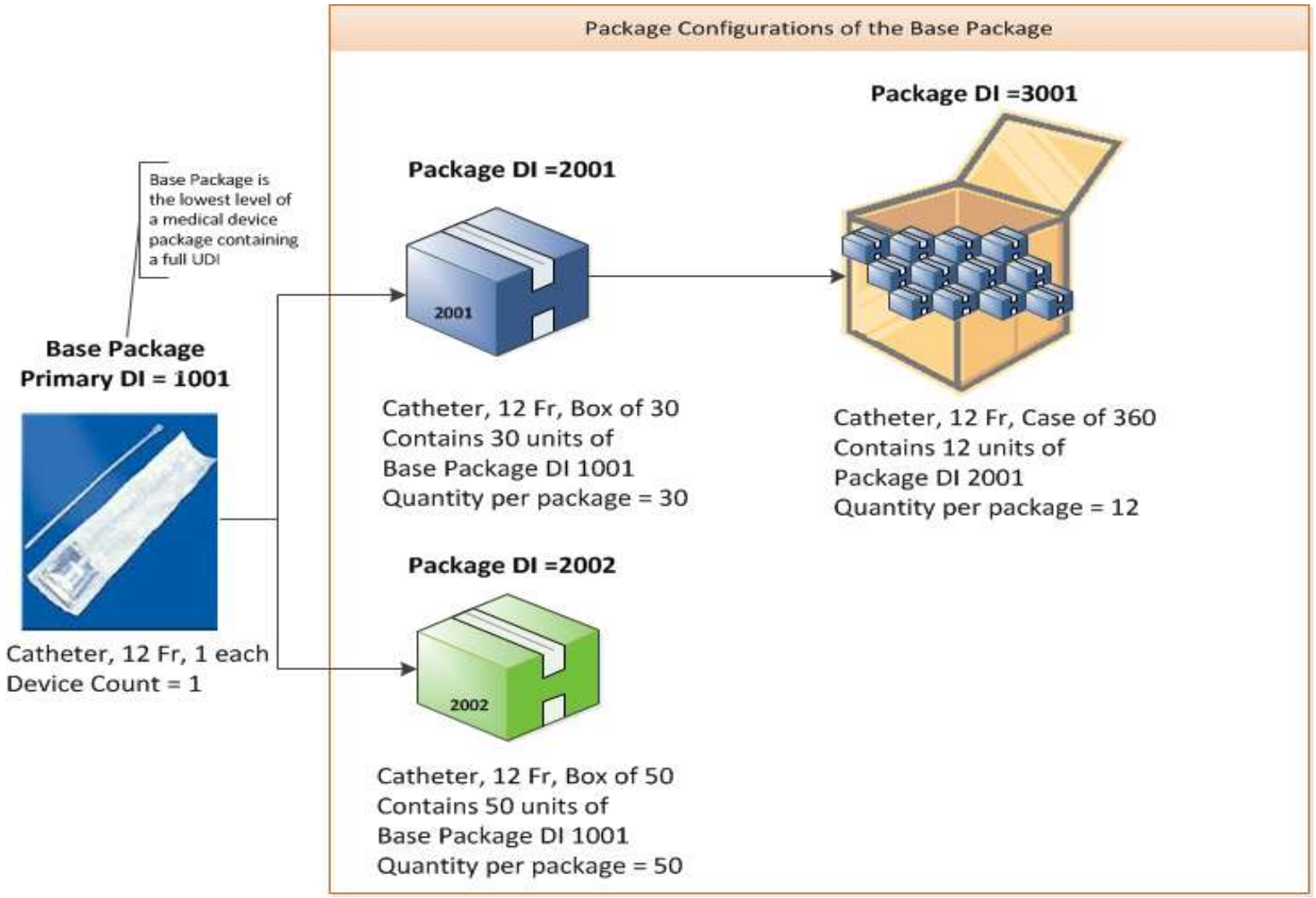
- lot, batch or serial number,
- expiration date or date of manufacture
- HCT/P's regulated as devices: the required distinct identification code.

Device Package

A device package contains a fixed quantity of a particular version or model of a device

Each level of packaging requires a different UDI

Levels of Packaging



Shipping Containers are Not Device Packages and Do Not Require a UDI

Direct Marking

In addition to its label, the device itself must also bear a permanent marking UDI if the device is:	• intended to be used more than once, and • intended to be reprocessed before each use.
UDI may be provided through either or both of the following:	• Easily readable plain text • AIDC technology or any alternative technology, that will provide UDI on demand
The direct mark UDI may be:	• identical to the UDI that appears on the label of the device, or • different UDI used to distinguish the unpackaged device from any device package containing the device

Labeler

Labeler is responsible for UDI requirements

Defined under 21 CFR 801.3 as

any person who causes a label to be:

- Applied to a device with the intent that the device will be commercially distributed; or
- Replaced or modified with the intent that the device will be commercially distributed

Labeler Examples

- Manufacturer
- Contract Manufacturer
- Private label distributor
- Convenience Kit Assembler

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Standards

UDI regulations require UDIs:

- Be issued under a system operated by an FDA-accredited issuing agency
- Conform to each of the following international standards:
  - ISO/IEC 15459-2
  - ISO/IEC 15459-4
  - ISO/IEC 15459-6
- Use only characters and numbers from the invariant character set of ISO/IEC 646

Issuing Agency (IA)

FDA accreditation requires that the issuing agency's system conforms to the ISO standards incorporated into the UDI Rule.

Accreditation is granted for an initial term of 3 years; may be renewed upon submission and FDA approval of a renewal application; may be revoked by the FDA.

Creating DIs

The UDI rule requires all UDIs to be issued under a system operated by an FDA-accredited issuing agency.

An issuing agency operates a system for issuing UDIs to labelers.

Each labeler receives unique labeler identifier from issuing agencies

Using the issuing agency system, the labeler then establishes DIs for each version or model of its devices.

2014-01-02

Dates on the device label must be in specified format

Date Format

Applies to dates on label

- Expiration date
- Manufacturing date
- Any other dates on the label intended to be brought to the attention of the user

Format: year-month-day
Ex: 2014-01-30

General UDI compliance dates apply

Summary of Basic UDI Requirements

Device label and device packages must bear a UDI

GUDID Global Unique Device Identification Database

Key data for these devices must be submitted to GUDID

Key data must be submitted to GUDID

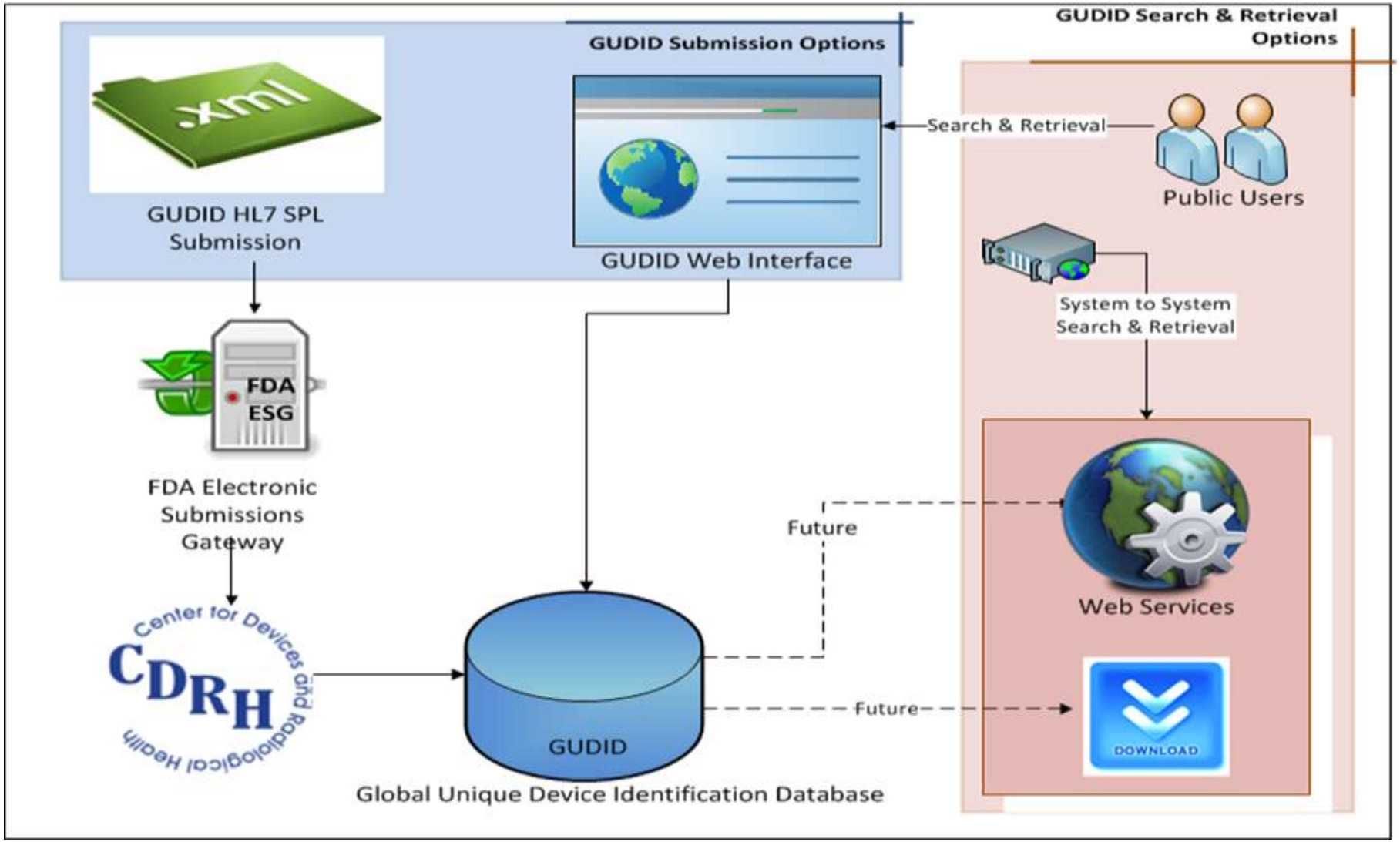
GUDID

Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to or stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI

GUDID Overview



GUDID Data Elements

General	Categorization	Flags: (Yes or No)
• Company Name • Device Identifier • Brand Name • Model Number • FDA Premarket #	• Global Medical Device Nomenclature (GMDN) • SNOMED (NLM) • FDA Product Code	• Rx • OTC • HCT/P • Combination Product • Requires Sterilization Prior to Use • Kit • For Single Use

GUDID Data Elements Cont.

Patient Safety

- Labeled as containing Latex
- Packaged as Sterile
- What MRI safety information does the labeling contain?

Production Identifier Flags:

- Lot or Batch Number
- Serial Number
- Expiration Date
- Manufacture Date
- Donation Identification Number

GUDID DI Screen (First of Five)

Device Information

Device Identifier (DI) Information

Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
HIBCC	wsDIOverview	1	

Labeler DUNS Number: *	Company Name:	Company Physical Address:
039169488	Safeway Grocery	4551 Forbes Blvd, Lanham, MD 207064389

Brand Name: *	Version or Model Number: *	Catalog Number:
DIOverview	123456	123456

Device Description (max 2000 characters):

DIOverviewRecord

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): *	Commercial Distribution End Date (yyyy-mm-dd):	Commercial Distribution Status:
2014-05-09		In Commercial Distribution

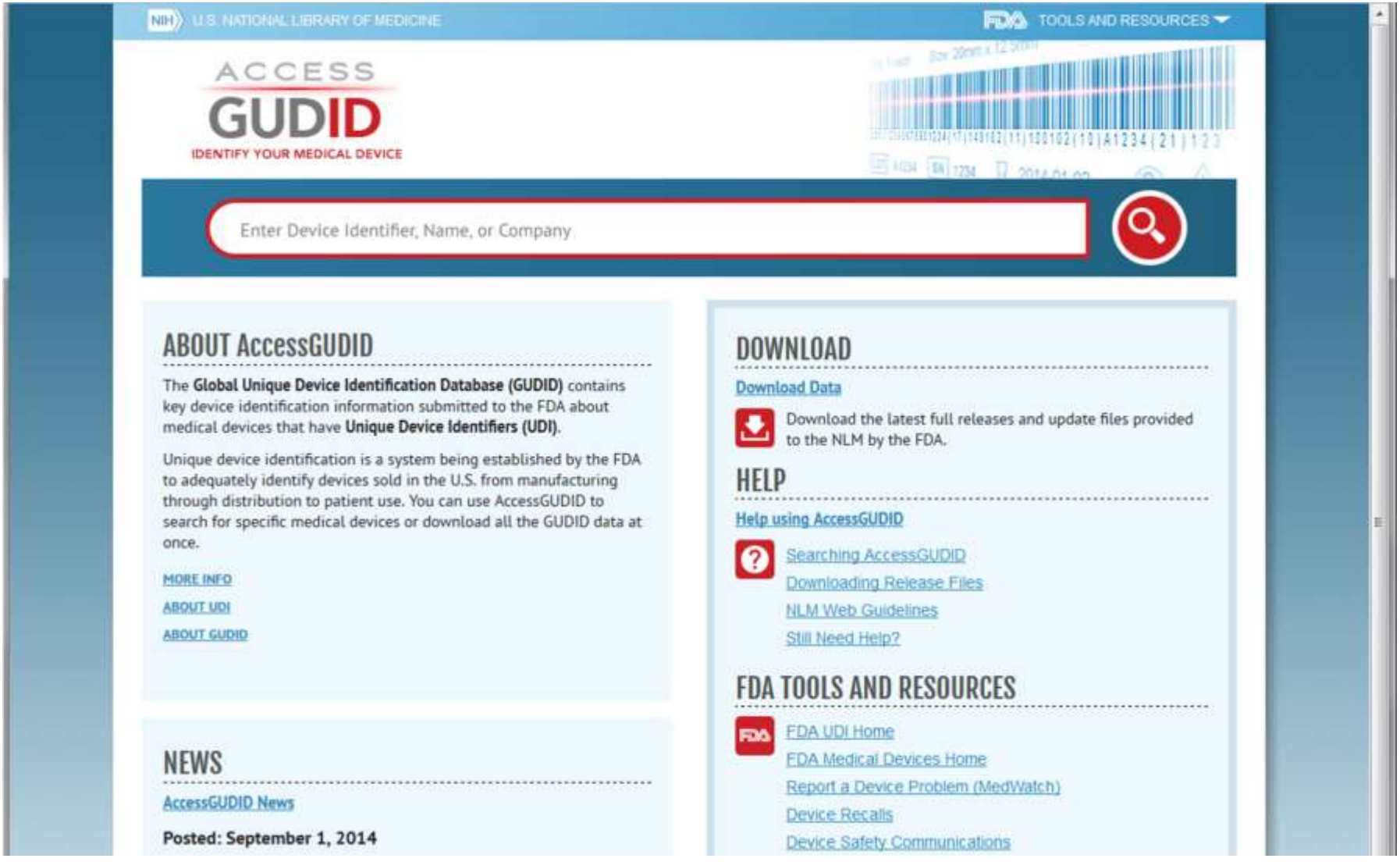
GUDID Submissions

The labeler should submit data to GUDID no later than 15 calendar days after the date the label of the device must bear a UDI

GUDID Data Elements Table

Submit to FDA an update to the information required by 21 CFR 830.310

AccessGUDID



AccessGUDID

Compliance Dates for UDI Requirements

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Exceptions and Alternatives

General exceptions under 21 CFR 801.30

FDA may grant an individual exception or alternative.

FDA will post individual exception/alternative grants on the UDI website.

Key General Exceptions

General exceptions from UDI labeling and data submission requirements include*

- Class I cGMP exempted devices
- Individual single-use devices sold and stored in a single package until removed for use
- IDEs or devices used solely for nonclinical use
- Devices intended solely for export from the US
- Individual devices in convenience kits
- Three year "grandfather"

*See 21 CFR 801.30 for full list of exceptions

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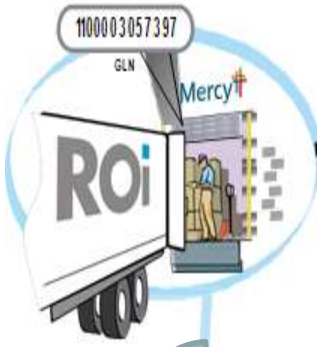
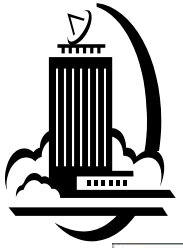
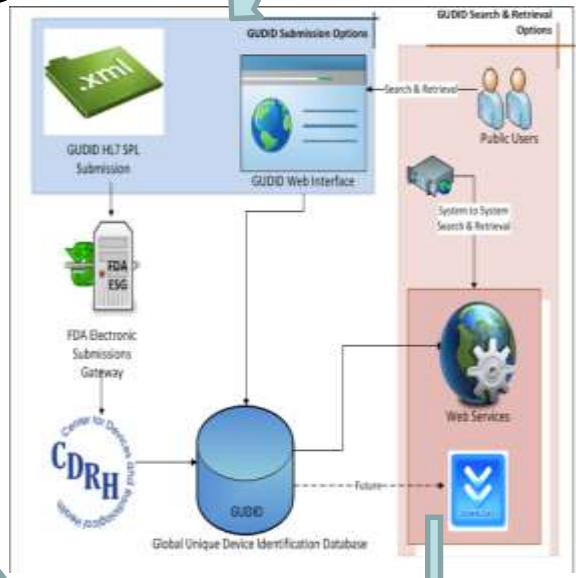
Vision for UDI Adoption



UDI Labeled Device to Care Provider



Company submits data to GUDID



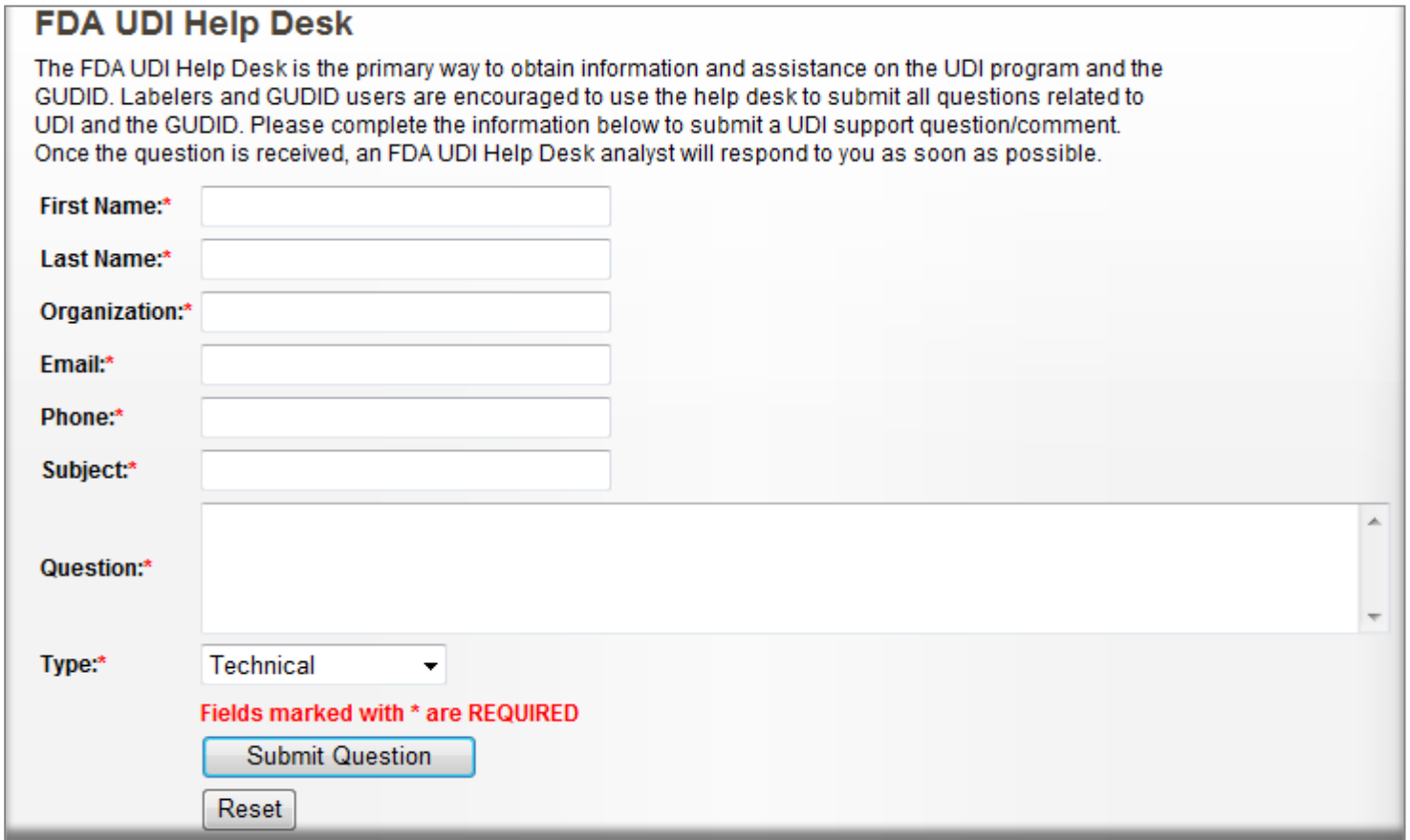
Device used on patient

Document Device Use

GUDID as source of standard device information

FDA UDI Help Desk

- **Submit question via the web, www.fda.gov/udi**
- **Please complete all fields on the web form!**



FDA UDI Help Desk

The FDA UDI Help Desk is the primary way to obtain information and assistance on the UDI program and the GUDID. Labelers and GUDID users are encouraged to use the help desk to submit all questions related to UDI and the GUDID. Please complete the information below to submit a UDI support question/comment. Once the question is received, an FDA UDI Help Desk analyst will respond to you as soon as possible.

First Name:*

Last Name:*

Organization:*

Email:*

Phone:*

Subject:*

Question:*

Type:* Technical

Fields marked with * are REQUIRED

Submit Question

Reset

Additional Resources

www.fda.gov/udi

- FDA Webinar: The Unique Device Identification Program (UDI 101)
- FDA Webinar: Getting Ready for GUDID
- FDA Webinar: Device Identifier Record
- FDA Webinar: GUDID HP7 SPL Submission Option Overview
- GUDID Database Elements Reference Table
- UDI Issuing Agencies

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D2S6

Final Thoughts